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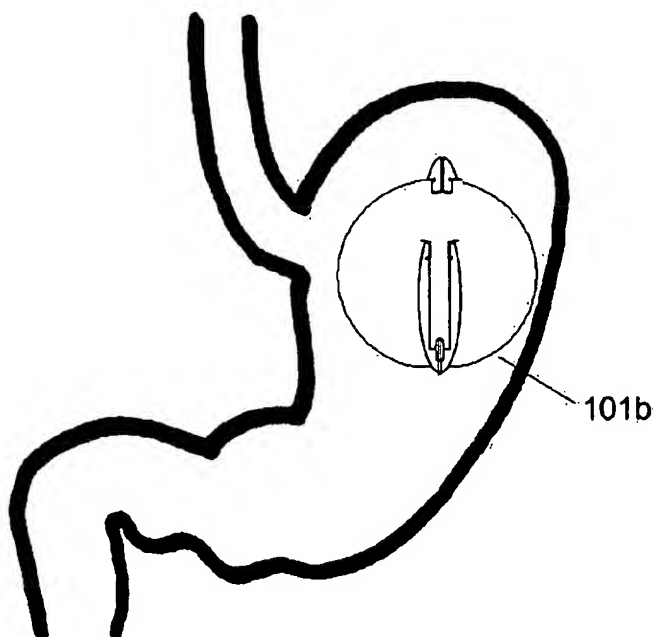
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(54) Title: A SYSTEM AND A METHOD FOR TREATING OF OBESITY BY USE OF AN INTRAGASTRIC BALLOON



(57) Abstract: The present invention relates to a system and a method for treating of obesity by use of an intragastric balloon adapted to be inflated or deflated inside the stomach of a patient for treating obesity by reducing the stomach volume. The system comprises an intragastric balloon, and regulating electrical circuitry having one or more signal outputs to thereby provide one or more voltage differences for at least partly regulating inflating and/or deflating of the balloon. The balloon and the regulating electrical circuitry is connected together so as to at least partly form an integral intragastric device. The method comprises disposing in the stomach of the patient an intragastric device comprising an intragastric balloon and a regulating electrical circuitry having one or more signal outputs to thereby provide one or more voltage differences for at least partly regulating inflating and/or deflating of the balloon, and actuating the regulating electrical circuitry to thereby provide one or more voltage differences to thereby actuate one or more fillant sources for inflating the balloon. The regulating electrical circuitry may be adapted to inductively receive an externally applied electric

control signal. The regulating electrical circuitry may also be adapted to inductively receive an externally applied electric power signal. It is preferred that the intragastric device comprises a transponder including at least part of said regulating electrical circuitry, said transponder thereby having one or more signal outputs for providing the one or more voltage differences for at least partly regulating inflating and/or deflating of the balloon.



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A SYSTEM AND A METHOD FOR TREATING OF OBESITY BY USE OF AN INTRAGASTRIC BALLOON

FIELD OF THE INVENTION

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The present invention relates to an intragastric balloon device adapted to be inflated inside the stomach of a patient for treating obesity by reducing the stomach volume.

10 BACKGROUND OF THE INVENTION

Biological and human clinical research has shown utility of treating obesity in humans by reducing the stomach volume.

15 U.S. Pat. No. 6,733,512 is generally directed to an intragastric balloon device adapted to be inserted into the stomach for treating obesity in humans by reducing the stomach volume. The intragastric balloon device includes a flexible, inflatable balloon having an interior chamber defining a volume. A portion of the balloon has a self-sealing valve thereon to facilitate the introduction of an
20 insufflation catheter into the interior chamber and to facilitate sealing of the catheter track upon removal of the insufflation catheter. The volume of the interior chamber, and the volume occupied by the balloon within the stomach of a patient, is adjusted by injecting an inflation fluid into the balloon's interior chamber. The balloon further includes a deflation valve in a portion thereof. The
25 deflation valve is a patch that has a bioabsorbable or biodegradable portion. The patch forms a portion of the wall of the balloon and is in leakproof engagement therewith. After the balloon has resided within the stomach for a predetermined period of time, the deflation valve becomes leaky due to disintegration of the bioabsorbable or biodegradable material and the balloon deflates within the
30 stomach, thereafter to be passed through the patient's digestive tract and excreted. The residence time of the balloon within the stomach depends upon the choice of biodegradable material incorporated into the patch and the construction of the deflation valve.

U.S. Pat. No. 6,676,674 is generally directed to a gastric band of a belt type is presented for attaching around a circumference of a patient's stomach, so as to define the diameter of the stomach opening. The band comprises outer and inner surfaces, wherein the inner surface engages the stomach, and at least the outer
5 surface is formed by an elongated member substantially non-extendable along a longitudinal axis thereof. A through-going opening is made in the elongated member and is located so as to define an end portion of the band having a predetermined length. An opposite end portion of the band is shaped so as to be insertable into the through-going opening for adjusting a desired inner diameter
10 of the band in its closed operating position and fastening the opposite end portion to the outer surface of the band.

U.S. Pat. No. 6,600,953 is generally directed to an apparatus for treating a condition such as obesity. The apparatus includes a set of one or more
15 electrodes, which are adapted to be applied to one or more respective sites in a vicinity of a body of a stomach of a patient. A control unit is adapted to drive the electrode set to apply to the body of the stomach a signal, configured such that application thereof increases a level of contraction of muscle tissue of the body of the stomach, and decreases a cross-sectional area of a portion of the body of the
20 stomach for a substantially continuous period greater than about 3 seconds.

U.S. Pat. No. 5,234,454 is generally directed to a method for controlling the body weight of a patient employs a percutaneous intragastric balloon catheter (10). The method comprises the first steps of inserting a percutaneous intragastric
25 balloon catheter (10) into the stomach of the patient through a gastrostomy tract. The intragastric balloon catheter (10), in turn, comprises elongated shaft means (11) having first (12) and second (13) ends, a first inflatable balloon (14) carried proximal to the first end; a second inflatable balloon (15) carried proximal to the first inflatable balloon, the second balloon having a lesser inflated volume than
30 the first balloon; first and second inflation lumens (18, 20); first and second inflation ports (22, 23) communicating respectively with the first and second inflation lumens and the first and second balloons, which ports are carried by the second end (13); a drainage lumen (16) passing between said first and second ends. The method continues by inflating the first and second balloons within the

patient, partially filling the stomach to provide satiety. The intragastric balloon catheter employed is also deemed to be novel.

U.S. Pat. No. 4,899,747 is generally directed to a stomach insert for treating
5 obesity in humans by reducing the stomach volume comprises a flexible, free
floating and unattached, inflatable balloon, the balloon being inflatable to a
volume effective to reduce the stomach volume of a person being treated. At
least a portion of the balloon has a self-sealing substance to facilitate puncture
thereof with insufflation means through which the balloon is inflated and to
10 facilitate sealing of the puncture upon removal of the insufflation means. The
method herein comprises positioning the balloon inside the stomach of the
person being treated for obesity so as to reduce the stomach volume.

U.S. Pat. No. 4,694,827 is generally directed to a balloon insertable and inflatable
15 in the stomach to deter ingestion of food and having, when inflated, a plurality of
smooth-surfaced convex protrusions disposed to permit engagement of the
stomach wall by the balloon only at spaced localities, for minimizing mechanical
trauma of the stomach wall by the balloon.

U.S. Pat. No. 6,615,084 is generally directed to an improved process using
20 electrostimulation for treating obesity, especially morbid obesity, and other
syndromes related to motor disorders of the stomach is provided. The improved
method of this invention provides electrostimulation on the lesser curvature of the
stomach, preferably on the lower or distal end of the lesser curvature, which
25 provides improved control of obesity and other syndromes related to motor
disorders of the stomach. In one embodiment, the process employs stimulation of
the lesser curvature at a rate of about 2 to about 14 pulses/minute with each
pulse lasting about 0.5 to about 4 seconds such that there is a pause of about 3
to about 30 between the pulses. Preferably, the pulse rate is about 12
30 pulses/minute with each pulse lasting about 2 seconds with a pause of about 3
seconds between pulses. Preferably, the pulse amplitude is about 0.5 to about 15
milliamps. More preferable, each pulse consists of a train of micro-bursts with a
frequency of about 5 to about 100 sec-1.

SUMMARY OF THE INVENTION

An aim of the present invention is to provide an improved system and an improved method for treating obesity in humans by reducing the stomach volume.

5

Thus, according to a first aspect of the present invention there is provided an apparatus for reducing the stomach volume, said apparatus comprising: an intragastric transponder being a single unit comprising RF wireless signal receiving means, electrical signal processing means and transformer means for transforming wireless energy from a received RF wireless signal into electric energy to supply said electrical signal processing means, said transponder having first and second signal outputs to thereby provide a voltage difference for inflating or deflating a balloon inside the stomach, said first and second signal outputs being in electrical contact with the electrical signal processing means of the transponder; and an external stimulator comprising a power source, electrical control means, and RF wireless signal transmitting means being capable of transmitting a RF signal to the RF wireless signal receiving means of the transponder, whereby said external stimulator controls the volume of the device being the balloon.

20

In a preferred embodiment of the first aspect of the invention the apparatus is adapted for an intragastric balloon device adapted to be inflated inside the stomach for treating obesity in humans by reducing the stomach volume.

25 It is preferred that the transponder has no wiring, electrodes or conductors reaching more than 2 mm from the exterior of the housing of the transponder, and it is even more preferred that the transponder has no wiring, electrodes or conductors reaching outside the exterior of the housing of the transponder.

30 It is preferred that the frequency of the RF-signal is in the range of 100-200 kHz or in the range of 125-150 kHz.

In a preferred embodiment, the transponder has an elongated form with a first and a second end, and wherein the balloon is encapsulated.

35

The intragastric balloon device may include a flexible, inflatable balloon having an interior chamber defining a volume and one or more transponders.

According to a second aspect of the invention there is provided a method and an apparatus for wireless treating of obesity by use of an intragastric balloon device adapted to be inflated or deflated inside the stomach of a patient for treating obesity in humans by reducing the stomach volume, said apparatus comprising: an intragastric balloon device being a single unit comprising RF wireless signal receiving means, electrical signal processing means and transformer means for transforming wireless energy from a received RF wireless signal into electric energy to supply said electrical signal processing means, said transponder having first and second signal outputs to thereby provide a voltage difference inflating or deflating of balloon, said external stimulator comprising a power source, electrical control means, and RF wireless signal transmitting means being capable of transmitting a RF signal to the RF wireless signal receiving means of the transponder, whereby said external stimulator controls the inflating or deflating of the balloon inside the patients stomach.

For the apparatus of the second aspect of the invention it is preferred that the intragastric device has no wiring, electrodes or conductors reaching outside the exterior of the housing of the device.

For the apparatus of the second aspect of the invention it is preferred that the frequency of the RF-signal is in the range of 100-200 kHz or in the range of 125-150 kHz.

For the apparatus of the second aspect of the invention it is preferred that intragastric device has an elongated form with a first and a second end.

According to an embodiment of the invention it is preferred that the intragastric device makes use of a compressor or pump to regulate the volume of the balloon. It is also preferred that the intragastric device makes use of electrolysis to regulate the volume of the balloon. Alternatively or additional, the intragastric device may use fuel cells to regulate the volume of the balloon.

It is preferred that the intragastric device uses a valve to regulate the volume of the balloon.

It is within a preferred embodiment that a pressure gauge is added to the
5 intragastric device to measure the pressure in the stomach and/or the balloon.

It is also within an embodiment of the invention that the intragastric device makes use of a chemical process to regulate the volume of the balloon.

10 According to a third aspect of the invention there is provided a medical system for treating of obesity by use of an intragastric balloon adapted to be inflated or deflated inside the stomach of a patient for treating obesity by reducing the stomach volume, said system comprising: an intragastric balloon, and regulating electrical circuitry having one or more signal outputs to thereby provide one or
15 more voltage differences for a least partly regulating inflating and/or deflating of the balloon, said balloon and said regulating electrical circuitry being connected together so as to at least partly form an integral intragastric device.

For the third aspect of the invention it is preferred that the regulating electrical
20 circuitry is adapted to inductively receive an externally applied electric control signal. It is also preferred that the regulating electrical circuitry is adapted to inductively receive an externally applied electric power signal.

For the third aspect of the invention it is preferred that the intragastric device
25 comprises a transponder including at least part of or all of the regulating electrical circuitry, said transponder thereby having one or more signal outputs for providing the one or more voltage differences for a least partly regulating inflating and/or deflating of the balloon. Here, the transponder may comprise RF wireless signal receiving means, electrical signal processing means and transformer
30 means for transforming wireless energy from a received RF wireless signal into electric energy to supply said electrical signal processing means, and the signal output(s) may be controlled by the electrical processing means of the transponder. It is preferred that the system of the third aspect of the invention further comprises an external stimulator having a power source, electrical control
35 means, and RF wireless signal transmitting means being capable of transmitting

a RF signal to the RF wireless signal receiving means of the transponder, whereby the external stimulator is adapted to provide one or more inputs to the signal processing means of the transponder to thereby control the signal output(s) of the transponder.

5

For the system of the third aspect of the invention, the regulating electrical circuitry or transponder may be arranged inside the balloon. Alternatively, the regulating electrical circuitry or the transponder may be arranged outside the balloon, when the balloon is inflated. Also for the system of the third aspect of the invention it is preferred that the intragastric device has no wiring, electrodes or
10 conductors reaching outside the exterior of the housing of the device.

According to an embodiment of the third aspect of the invention, the externally applied electric signal(s) may be wireless RF-signals. Here, the frequency of the
15 RF-signal(s) may be in the range of 100-200 kHz or in the range of 125-150 kHz.

Also for the third aspect of the invention it is preferred that the intragastric device has an elongated form with a first and a second end when the balloon is in a deflated position.

20

According to an embodiment of the system of the third aspect of the invention, the intragastric device may further comprise a pump or a compressor for introducing a fillant to the balloon to thereby inflate the balloon. Here, the pump or compressor may further be adapted for removing the fillant from the balloon to
25 thereby deflate the balloon. It is preferred that the pump or compressor is controlled by a voltage difference provided by a signal output of the regulating electrical circuitry. Here, the signal output may be a first signal output and the voltage difference may be a first voltage difference.

It is also within an embodiment of the third aspect of the invention that the intragastric device further comprises a gas reservoir for at least partly inflating the balloon. Here, the intragastric device may further comprise an actuator for activating said gas reservoir to thereby at least partly inflating the balloon. It is preferred that the actuator is controlled by a voltage difference provided by a
30 signal output of the regulating electrical circuitry, which signal output may be a
35

second signal output and which voltage difference may be a second voltage difference.

5 It is also within an embodiment of the third aspect of the invention that the intragastric device further comprises a valve for at least partly regulating the inflation and/or deflation of the balloon. Here, the valve is preferably controlled by a voltage difference provided by a signal output of the regulating electrical circuitry.

10 According to an embodiment of the third aspect of the invention, the intragastric device may be adapted for inflating the balloon with a biocompatible fillant of at least one of a liquid, a gas and a gel.

15 It is also within an embodiment of the third aspect of the invention that the intragastric device is adapted for using electrolysis to provide a gas for at least partly inflating the balloon. Here, the electrolysis is preferably controlled by a voltage difference provided by a signal output of the regulating electrical circuitry. Alternatively or additionally, the intragastric device may be adapted for using fuel cells to regulate the inflation and/or deflation of the balloon.

20 The third aspect of the invention also covers an embodiment wherein the intragastric device is adapted for using a chemical process to regulate the inflation and/or deflation of the balloon.

25 For the third aspect of the invention it is preferred that the integral intragastric device comprises a power source for supplying operating power to the regulating electrical circuitry. Here, the power source may be at least one of a battery, a rechargeable battery and a capacitor.

30 According to the third aspect of the invention there is also provided a method for treating of obesity by use of an intragastric balloon adapted to be inflated or deflated inside the stomach of a patient for treating obesity by reducing the stomach volume, said method comprising: disposing in the stomach of the patient an intragastric device comprising an intragastric balloon and a regulating
35 electrical circuitry having one or more signal outputs to thereby provide one or

more voltage differences for at least partly regulating inflating and/or deflating of the balloon; and actuating the regulating electrical circuitry to thereby provide one or more voltage differences to thereby actuate one or more fillant sources for inflating the balloon.

5

For the method of the third aspect of the invention it is preferred that the regulating electrical circuitry is adapted to inductively receive an externally applied electric control signal. It is also preferred that the regulating electrical circuitry is adapted to inductively receive an externally applied electric power

10 signal.

For the method of the third aspect of the invention it is preferred that the intragastric device comprises a transponder including at least part of or all of said regulating electrical circuitry, said transponder thereby having one or more signal

15 outputs for providing the one or more voltage differences for a least partly regulating inflating and/or deflating of the balloon. Here, the transponder may comprise RF wireless signal receiving means, electrical signal processing means and transformer means for transforming wireless energy from a received RF wireless signal into electric energy to supply said electrical signal processing

20 means, and the signal output(s) may be controlled by the electrical signal processing means of the transponder. It is furthermore preferred that an external stimulator is provided, said external stimulator having a power source, electrical control means, and RF wireless signal transmitting means being capable of transmitting a RF signal to the RF wireless signal receiving means of the

25 transponder, whereby said external stimulator is adapted to provide one or more inputs to the electrical processing means of the transponder to thereby control the signal output(s) of the transponder, and it is preferred that said actuating comprises providing one or more inputs to the electrical signal processing means of the transponder by means of the external stimulator.

30

For the method of the third aspect of the invention it is preferred that the method further comprises the step of inflating the balloon to occupy a large portion of the stomach of the patient to provide a feeling of satiety.

The method of the third aspect of the invention also covers an embodiment, wherein the intragastric device further comprises a gas reservoir, and wherein the actuating of one or more fillant sources comprises actuating the regulating electrical circuitry to provide a voltage difference for actuating the gas reservoir to thereby at least partly inflating the balloon.

It is also within an embodiment of the third aspect of the invention that the intragastric device further comprises a pump or a compressor for introducing a fillant to the balloon to thereby inflate the balloon, and wherein the actuating of one or more fillant sources comprises actuating the regulating electrical circuitry to provide a voltage difference for actuating the pump or compressor to thereby at least partly inflating the balloon.

The method of the third aspect of the invention also covers an embodiment, wherein the actuating of one or more fillant sources comprises the use of electrolysis to provide a gas for at least partly inflating the balloon. Here, the gas provided by the electrolysis may be pumped into the balloon by the pump to thereby at least partly inflating the balloon.

The present invention also covers one or more embodiments of an apparatus or system of the present invention further being adapted for providing electro stimulation for obesity. It is also within an embodiment of a method of the present invention that the method further comprises electro stimulation for obesity. It is preferred that the pulse rate is about 12 pulses/minute with each pulse lasting about 2 seconds with a pause of about 3 seconds between pulses. Preferably, the pulse amplitude is about 0.5 to about 15 milliamps. More preferable, each pulse consists of a train of micro-bursts with a frequency of about 5 to 100 sec⁻¹.

The intragastric device of the present invention may be swallowed by the patient, and the volume of the interior chamber and the volume occupied by the balloon within the stomach of the patient, may be remotely increased by means of a transponder. Afterwards the dimensions of the balloon in the stomach are greater than the oesophageal opening and gastric outlet of the stomach.

The intragastric device may further include a deflation valve controlled by a transponder.

5 The volume of the balloon within the stomach of the patient can remotely be increased or decreased by transponders transforming wireless energy from a received RF wireless signal into electric energy.

10 After the balloon has resided within the stomach for a predetermined period of time the deflation valve may be activated by a remote-control. The balloon may then deflate within the stomach, thereafter to be passed through the patient's digestive tract and excreted.

The invention is described in more detail in the following with reference to the accompanying drawings.

15

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates an intragastric balloon device according to an embodiment of the invention in the stomach of a patient before inflation of the balloon,

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Fig. 2 illustrates the intragastric balloon device of Fig. 1 in the stomach of a patient after inflation of the balloon,

25 Fig. 3 illustrates the intragastric balloon device of Fig. 2 on its way out of the stomach of a patient after deflation of the balloon,

Fig. 4 shows an intragastric balloon device according to an embodiment of the invention with an inflated balloon,

30 Fig. 5 is a block diagram showing electronic components and other components being part of an intragastric balloon device according to an embodiment of the invention,

35 Fig. 6 illustrates an external stimulator or pulse-generator according to an embodiment of the present invention,

Fig. 7 shows an intragastric balloon device in a deflated position according to an embodiment of the invention, and

- 5 Fig. 8 illustrates the use of an external stimulator for communicating with electrical circuitry arranged in the intragastric balloon device according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

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Fig. 1 illustrates an intragastric balloon device 101a according to an embodiment of the invention in the stomach of a patient before inflation of the balloon 102. The balloon 102 is flat packed inside the intragastric device prior to inflation.

- 15 Fig. 2 illustrates the intragastric balloon device 101b of Fig. 1 in the stomach of a patient after inflation of the balloon.

Fig. 3 illustrates the intragastric balloon device 101c of Fig. 2 on its way out of the stomach of a patient after deflation of the balloon.

20

- Fig. 4 shows an intragastric balloon device 101 according to an embodiment of the invention with an inflated balloon. According to an embodiment of the invention, the intragastric balloon device or intragastric device 101 may be constructed with an electronic unit 404 comprising such parts as: a pump engine or mechanism 501, a power unit or power supply 508, and control and
25 communications unit 503. A balloon 402 is mounted to the electronic unit 404.

- The balloon 402 may be a spherically shaped reservoir made out of very thin PUR. The PUR material is selected because of its strength and ability to sustain
30 the aggressive environment in the stomach. Furthermore this material has a proven track record from use in gastric balloons.

The balloon 402 may be high frequency welded to the final shape, welded to the electronic unit 404 and packaged into it to a pill shape, as illustrated in Fig. 7.

35

The manufacturing of the intragastric device 101 may be in a controlled environment, but need not be in a clean room as the device does not have to be sterile when delivered.

- 5 The balloon 402 may have one or more safety valves 401 to deflate the balloon 402 if desired. The safety valve 401 may be an organic valve, which may be dissolved during time, and such safety valve need not be controlled by the electronic unit 404. However, the intragastric device 101 may also comprise mechanically safety valves being controlled by the electronic unit 404. Such a
10 valve should be arranged in the vicinity of the electronic unit 404 having control circuitry for controlling the function of such a valve.

- In order to provide a gas for inflating the balloon 402, electrolysis means may be provided, and an electrical current may be applied between a pair of metal
15 electrodes 403 immersed in the gastric fluid.

- Fig. 5 is a block diagram showing an electronic unit 404 with electronic components and other components being part of an intragastric balloon device 101 according to an embodiment of the invention. In Fig. 5 there is a control and
20 communications unit 503, which is adapted for remote wireless communication, and which may include a controller, a memory and programmable logic. The electronic unit 404 further has a power supply 508. The power supply can be one of, or a combination of, a battery, a capacitor, electrolysis, and wireless energy by means of induction (electromagnetic or RF). When the power supply comprises a
25 battery, this may be a rechargeable battery. The electronic unit 404 may also comprise a micro actuator 504 for controlling a gas reservoir 506 and a safety valve 505. The electronic unit 404 may also comprise a pump engine 501, electrolysis means 502 and communication interface circuitry 507 for communicating with an external stimulation or control circuit 801.

- 30 The safety valve 505 may be used to deflate the balloon 101. This deflation may either be by the performed on a pre-programmed, predetermined time, or by the remote wireless communication device 503 or if the electronic unit 404 or the intragastric device 101 ceases to work properly.

The gas reservoir 506 should contain a gas under pressure. When the correct placement of the intragastric balloon device 506 is asserted by the Physician the micro actuator 504 may be activated by the control unit 503 to release the gas under pressure from the reservoir to inflate the balloon. The gas reservoir 506
5 should contain enough gas to partly or fully inflate the balloon 402 in the stomach of the patient. This may prevent the balloon 402 from passing through the patient's digestive tract. The gas reservoir 506 may be a MEMS (Micro Electro Mechanical System) device. After this initial inflation boost the pump engine 501 may take over the control of further inflating the balloon 402. The pump engine
10 501 may be a MEMS (Micro Electro Mechanical System) device, and may be controlled by the control unit 503 to inflate and/or deflate the balloon.

The communication interface 507 of the electronic unit 404 may be adapted for communication with an external stimulator 801 by use of wireless communication,
15 such as RF (Radio Frequency), induction, IrDA and/or Bluetooth.

The safety valve 505 may be a MEMS (Micro Electro Mechanical System) valve device, which can be driven by electrostatic forces.

20 The power source or supply 508 may be a power source for supplying operating power to the electronic circuitries, and recharging and programming the power source may be performed as needed from an external stimulator or control circuit 801. The power source 508 may be recharged with sufficient energy to allow the integral intragastric device to provide continuous or intermittent operation.

25 In order to provide a gas for the pump engine 501 to inflate the balloon 402, electrolysis means 403, 502 is provided. In order for the electrolysis means 403, 502 to operate, an electrical current should be applied between the pair of metal electrodes 403 immersed in the gastric fluid of the patient. Each electrode
30 attracts ions which are of the opposite charge. Therefore, positively charged ions move towards the cathode, while negatively charged ions move toward the anode. The energy required to separate the ions, and cause them to gather at the respective electrodes, is provided by the electrical power supply 508. At the probes 403, electrons are absorbed or released by the ions, forming a gas that
35 can be used to inflate the balloon.

It is preferred that the electronic parts, 503, 504, 507 and 508, are comprised in a single unit being a transponder, which is able to receive and transmit signals by wireless communication to the external control circuit 801.

5

Fig. 6 illustrates an external stimulator 801 or pulse-generator according to an embodiment of the present invention. The external stimulator 801 may comprise a power source, electrical control means, and RF wireless signal transmitting means being capable of transmitting a RF signal to the RF wireless signal receiving means of the transponder, whereby the external stimulator 801 may control the volume of the balloon 402.

10

Fig. 7 shows an intragastric balloon device 101a in a deflated position according to an embodiment of the invention. In Fig.7 the balloon is flat packed inside the intragastric device, but part of the balloon also covers the outer part of the device 101a.

15

Fig. 8 illustrates the use of an external stimulator 801 for communicating with electrical circuitry arranged in the intragastric balloon device 101b according to an embodiment of the invention.

20

While the invention has been particularly shown and described with reference to particular embodiments, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention, and it is intended that such changes come within the scope of the following claims.

25

CLAIMS

1. A medical system for treating of obesity by use of an intragastric balloon adapted to be inflated or deflated inside the stomach of a patient for treating
5 obesity by reducing the stomach volume, said system comprising:
an intragastric balloon, and
regulating electrical circuitry having one or more signal outputs to thereby provide one or more voltage differences for a least partly regulating inflating and/or deflating of the balloon,
10 said balloon and said regulating electrical circuitry being connected together so as to at least partly form an integral intragastric device.
2. A system according to claim 1, wherein the regulating electrical circuitry is adapted to inductively receive an externally applied electric control signal.
15
3. A system according to claim 1 or 2, wherein the regulating electrical circuitry is adapted to inductively receive an externally applied electric power signal.
- 20 4. A system according to any one of the claims 1-3, wherein the intragastric device comprises a transponder including at least part of said regulating electrical circuitry, said transponder thereby having one or more signal outputs for providing the one or more voltage differences for a least partly regulating inflating and/or deflating of the balloon.
- 25 5. A system according to claim 4, wherein the transponder comprises RF wireless signal receiving means, electrical signal processing means and transformer means for transforming wireless energy from a received RF wireless signal into electric energy to supply said electrical signal processing means, and
30 wherein said signal output(s) is(are) controlled by the electrical processing means of the transponder.
6. A system according to claim 4 or 5, said system further comprising:

an external stimulator having a power source, electrical control means, and RF wireless signal transmitting means being capable of transmitting a RF signal to the RF wireless signal receiving means of the transponder,

whereby said external stimulator is adapted to provide one or more inputs
5 to the signal processing means of the transponder to thereby control the signal output(s) of the transponder.

7. A system according to any one of the claims 1-6, wherein the regulating electrical circuitry or transponder is arranged inside the balloon.

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8. A system according to any one of the claims 1-6, wherein the regulating electrical circuitry or the transponder is arranged outside the balloon, when the balloon is inflated.

15 9. A system according to any one of the claims 1-8, wherein the intragastric device has no wiring, electrodes or conductors reaching outside the exterior of the housing of the device.

20 10. A system according to any one of the claims 2-9, wherein the externally applied electric signal(s) is/are wireless RF-signals.

11. A system according to claim 10, wherein the frequency of the RF-signal(s) is/are in the range of 100-200 kHz or in the range of 125-150 kHz.

25 12. A system according to any one of the claims 1-11, wherein the intragastric device has an elongated form with a first and a second end when the balloon is in a deflated position.

30 13. A system according to any one of the claims 1-12, wherein the intragastric device further comprises a pump or a compressor for introducing a fillant to the balloon to thereby inflate the balloon.

14. A system according to claim 13, wherein the pump or compressor is further adapted for removing the fillant from the balloon to thereby deflate the balloon.

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15. A system according to any one of the claims 1-14, wherein the intragastric device further comprises a gas reservoir for at least partly inflating the balloon.
16. A system a according to 15, wherein the intragastric device further
5 comprises an actuator for activating said gas reservoir to thereby at least partly inflating the balloon.
17. A system according to any one of the claims 13-16, wherein the pump or compressor is controlled by a first voltage difference provided by a first signal
10 output of the regulating electrical circuitry.
18. A system according to claim 16 or 17, wherein the actuator is controlled by a voltage difference provided by a signal output of the regulating electrical circuitry.
15
19. A system according to claim 18, wherein the actuator is controlled by a second voltage difference provided by a second signal output of the regulating electrical circuitry.
20. A system according to any one of the claims 1-19, wherein the intragastric device comprises a valve for at least partly regulating the inflation and/or deflation of the balloon.
21. A system according to claim 19, wherein the valve is controlled by a voltage
25 difference provided by a signal output of the regulating electrical circuitry.
22. A system according to any one of the claims 1-21, wherein the intragastric device is adapted for inflating the balloon with a biocompatible fillant of at least one of a liquid, a gas and a gel.
- 30
23. A system according to any one of the claims 1-22, wherein the intragastric device is adapted for using electrolysis to provide a gas for at least partly inflating the balloon.

24. A system according to claim 23, wherein the electrolysis is controlled by a voltage difference provided by a signal output of the regulating electrical circuitry.
25. A system according to any one of the claims 1-12, wherein the intragastric
5 device is adapted for using fuel cells to regulate the inflation and/or deflation of the balloon.
26. A system according to any one of the claims 1-12, wherein the intragastric device is adapted for using a chemical process to regulate the inflation and/or
10 deflation of the balloon.
27. A system according to any one of the claims 1-26, wherein the integral intragastric device comprises a power source for supplying operating power to the regulating electrical circuitry.
15
28. A system according to claim 27, wherein the power source is at least one of a battery, a rechargeable battery and a capacitor.
29. A method for treating of obesity by use of an intragastric balloon adapted to
20 be inflated or deflated inside the stomach of a patient for treating obesity by reducing the stomach volume, said method comprising:
- disposing in the stomach of the patient an intragastric device comprising an intragastric balloon and a regulating electrical circuitry having one or more signal outputs to thereby provide one or more voltage differences for at least partly
25 regulating inflating and/or deflating of the balloon, and
- actuating the regulating electrical circuitry to thereby provide one or more voltage differences to thereby actuate one or more fillant sources for inflating the balloon.
30. A method according to claim 29, wherein the regulating electrical circuitry
30 is adapted to inductively receive an externally applied electric control signal.
31. A method according to claim 20 or 30, wherein the regulating electrical circuitry is adapted to inductively receive an externally applied electric power
35 signal.

32. A method according to any one of the claims 29-31, wherein the intragastric device comprises a transponder including at least part of said regulating electrical circuitry, said transponder thereby having one or more signal outputs for
5 providing the one or more voltage differences for a least partly regulating inflating and/or deflating of the balloon.

33. A method according to claim 32, wherein the transponder comprises RF wireless signal receiving means, electrical signal processing means and
10 transformer means for transforming wireless energy from a received RF wireless signal into electric energy to supply said electrical signal processing means, and wherein said signal output(s) is(are) controlled by the electrical signal processing means of the transponder.

34. A method according to claim 32 or 33, said wherein an external stimulator is provided, said external stimulator having a power source, electrical control means, and RF wireless signal transmitting means being capable of transmitting a RF signal to the RF wireless signal receiving means of the transponder, whereby said external stimulator is adapted to provide one or more inputs to the
20 electrical processing means of the transponder to thereby control the signal output(s) of the transponder, and wherein said actuating comprises providing one or more inputs to the electrical signal processing means of the transponder by means of the external stimulator.

35. A method according to any one of the claims 29-36, said method further comprising the step of inflating the balloon to occupy a large portion of the stomach of the patient to provide a feeling of satiety.

36. A method according to any one of the claims 29-35, wherein the intragastric device further comprises a gas reservoir, and wherein the actuating of one or
30 more fillant sources comprises actuating the regulating electrical circuitry to provide a voltage difference for actuating the gas reservoir to thereby at least partly inflating the balloon.

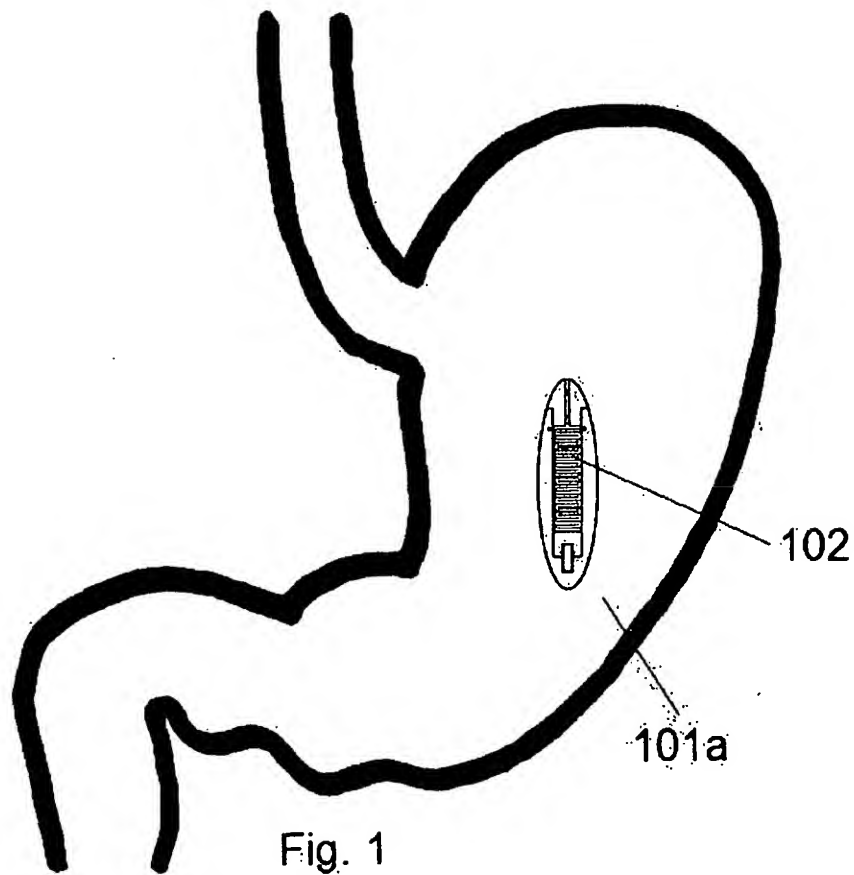
37. A method according to any one of the claims 29-36, wherein the intragastric device further comprises a pump or a compressor for introducing a fillant to the balloon to thereby inflate the balloon, and wherein the actuating of one or more fillant sources comprises actuating the regulating electrical circuitry to provide a voltage difference for actuating the pump or compressor to thereby at least partly inflating the balloon.

38. A method according to any one of the claims 29-37, wherein the actuating of one or more fillant sources comprises the use of electrolysis to provide a gas for at least partly inflating the balloon.

39. A method according claims 37 and 38, wherein the gas provided by the electrolysis is pumped into the balloon by the pump to thereby at least partly inflating the balloon.

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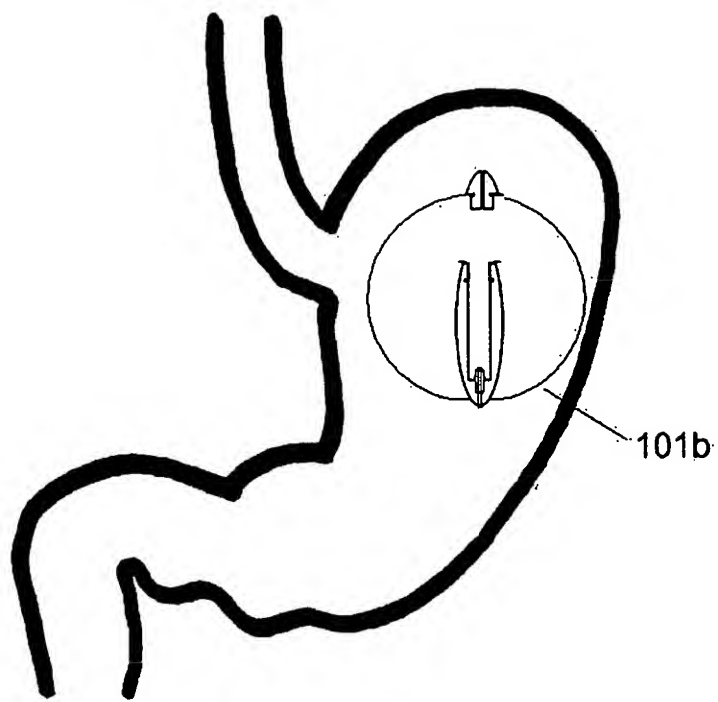


Fig. 2

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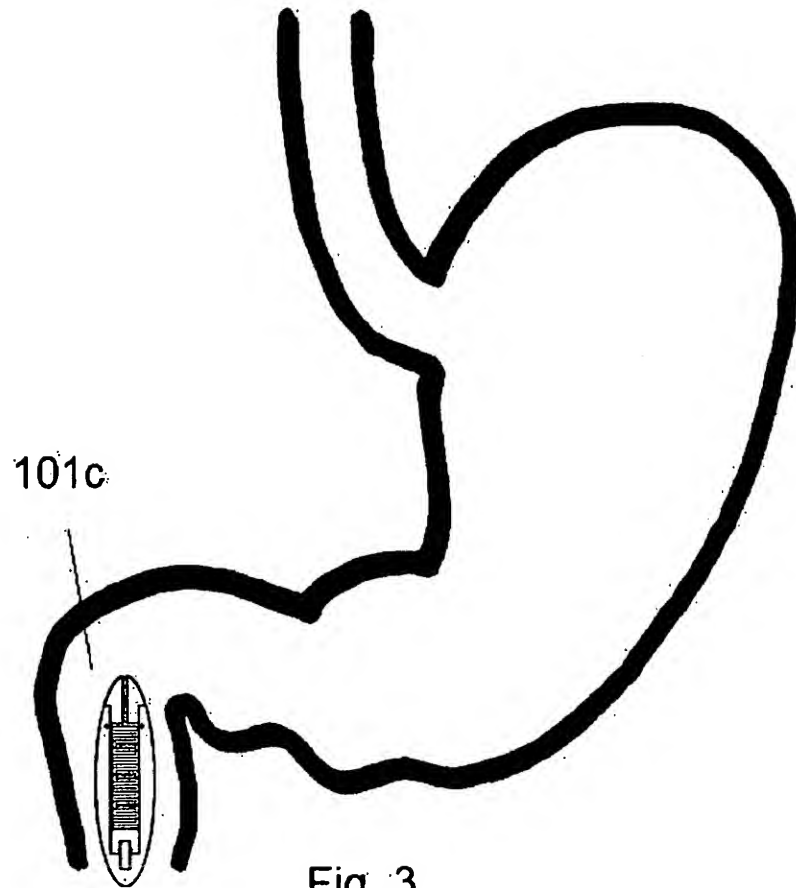


Fig. 3

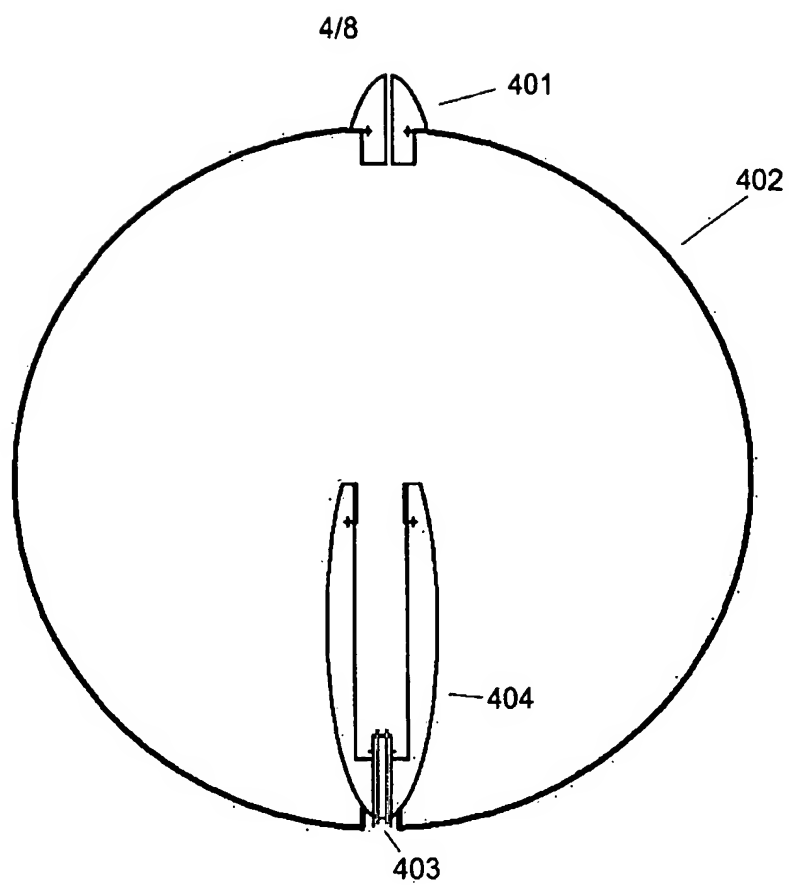


Fig. 4

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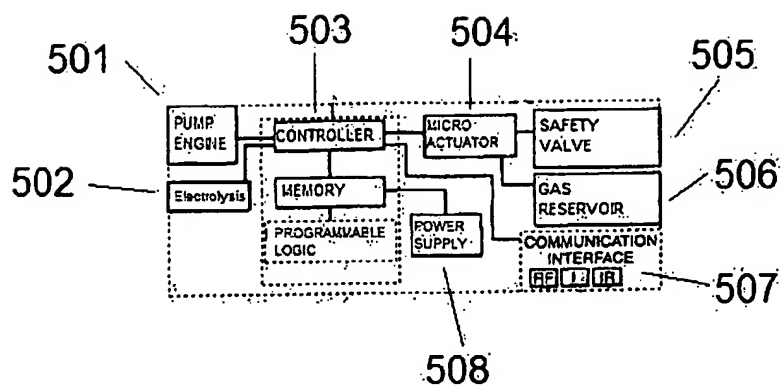


Fig. 5

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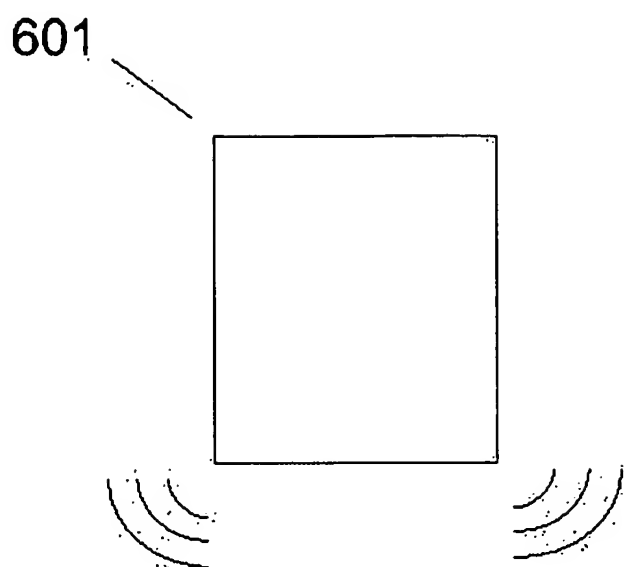


Fig. 6

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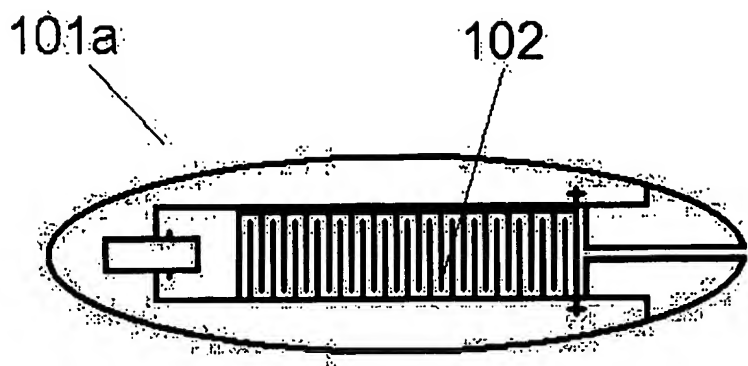


Fig. 7

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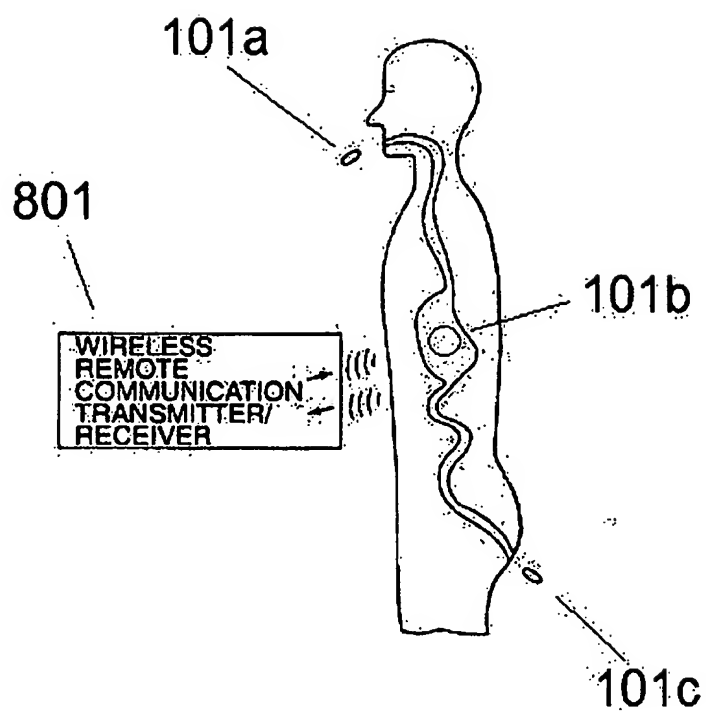


Fig. 8